§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

[48 FR 56948, Dec. 27, 1983]

§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, and the Director, Division of Standards Enforcement, Office of Compliance and Surveillance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

[55 FR 47054, Nov. 9, 1990]

§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

[48 FR 56949, Dec. 27, 1983]

§ 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505(c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director (Bioequivalence), Office of Generic Drugs, CDER.

[53 FR 18274, May 23, 1988, as amended at 55 FR 6247, Feb. 22, 1990]

§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

(b) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Directors and Deputy Directors of the Office of Drug Evaluation I and Drug Evaluation II, CDER.

(3) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I and Drug Evaluation II, CDER.

(4) The Director and supervisory consumer safety officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

[52 FR 2514, Jan. 23, 1987, as amended at 54 FR 8320, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990]